

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:22-md-03036-RJC**

**IN RE: GARDASIL PRODUCTS LIABILITY
LITIGATION**

MDL No. 3036

**THIS DOCUMENT RELATES TO
ALL CASES**

THIS MATTER comes before the Court on the Plaintiffs’ Motion to Compel (the “Motion”). (Doc. No. 36). Defendants Merck & Co., Inc. and Merck Sharp & Dohme LLC (together, “Merck”) oppose the Motion. For the reasons stated herein, the Motion is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

This is multi-district litigation (“MDL”) involving allegations “that [P]laintiffs . . . developed Postural Orthostatic Tachycardia Syndrome (POTS), [Primary Ovarian Failure (POF)/Primary Ovarian Insufficiency (POI)], and various other injuries as the result of an autoimmune reaction to [Merck’s] Gardasil vaccine.” (Doc. No. 1). In addition to this MDL, there are several individual state court actions in California with similar allegations against Merck. Prior to this MDL, the parties in the California state court actions engaged in extensive discovery, including related discovery disputes and negotiations. Ultimately, the Parties agreed that Merck’s discovery responses from the California actions will be available to the Plaintiffs in this MDL, and that the Parties will resolve related discovery disputes universally in this MDL. On November 18, 2022, Plaintiffs filed the Motion to Compel, in short, arguing that certain of Merck’s prior productions and interrogatory responses are deficient. (Doc. No. 36). Merck opposes the Motion.

(Doc. No. 48). The Court heard oral arguments on the Motion and opposition on February 28, 2023.

II. LEGAL STANDARD

Under Federal Rule Civil Procedure 26(b)(1), parties may obtain discovery regarding any nonprivileged matter that is: (1) relevant to any party's claim or defense; and (2) proportional to needs of the case. In considering proportionality, courts consider (1) the importance of the issues at stake in the action; (2) the amount in controversy; (3) the parties' relative access to relevant information; (4) the parties' resources; (5) the importance of the discovery in resolving the issues; and (6) whether the burden or expense outweighs its likely benefits. Fed. R. Civ. P. 26(b)(1). Information need not be admissible to be discoverable. *Id.* Under Federal Rule of Civil Procedure 37(a), a propounding party may move for an order compelling discovery where a party fails to respond or provides an evasive or incomplete response. The person "resisting discovery, not the party moving to compel discovery, bears the burden of persuasion." *Kinetic Concepts, Inc. v. ConvaTec, Inc.*, 268 F.R.D. 226, 243 (M.D.N.C. 2010) (collecting cases). The decision to compel discovery is within the "broad discretion" of the district court. *Cook v. Howard*, 484 Fed. App'x 805, 812 (4th Cir. 2012).

III. DISCUSSION

Plaintiffs' Motion asks the Court to compel: (1) further productions to Request for Production ("RFP") numbers 3–4, 10, 18–19, 32, 45–49, 55–56, 60–65, and 71–74; and (2) further responses to Interrogatory numbers 36, 78–80, and 86–87. The Court's ruling or direction on each is below.

No.	Request Summary	Ruling
RFP No. 62	Compel the entirety of Merck's Gardasil Adverse Events Databases, including the Merck Adverse Event Reporting and Review System ("MARRS").	GRANTED. The information in MARRS is relevant to Plaintiffs' claims and Merck's defenses. Plaintiffs' and their experts should have the same opportunity as Merck to review and analyze the entirety of the data. The discovery is also proportional to the needs of this MDL. Each proportionality factor in Rule 26(b)(1) leans in Plaintiffs' favor. Additionally, Merck's conceded during oral arguments that this request does not cause any undue burden, aside for the need to redact certain information, which is largely, although not entirely, automated.
RFP Nos. 3–4, 18–19, 60–61 & 63–65	Compel Merck to produce all Gardasil studies and analyses in Merck's possession, including all related communications and case report forms ("CFRs") for patients during clinical trials.	<p>DENIED IN PART. Plaintiffs' request to compel Merck to produce paper CFRs is denied. Producing paper CFRs would cause an undue burden on Merck and would be duplicative since the information is largely available in electronic format.</p> <p>As to Plaintiffs' remaining requests, the Court finds Plaintiffs' requests on their face are overly broad. <i>Health & Beauty Techs., Inc. v. Merz Pharma GmbH KGaA</i>, No. 7:18-CV-117-FL, 2018 WL 6345369, at *7 (E.D.N.C. Dec. 5, 2018). ("As a practical matter, Defendants cannot search every email inbox of every employee."). However, given the MDL posture, the need and proportionality for discovery in this case is greater than what Merck provided in single-plaintiff cases. Thus, the Court will require the Parties to meet and confer in an effort to reach agreement on additional search terms and/or running searches through additional custodial or non-custodial files for responsive documents to these requests. During these meet and confers, the Court expects both Parties to engage in the necessary discussions to facilitate meaningful negotiations, such as identifying specific, relevant custodial or non-custodial files where needed. The Court instructs both Parties to engage in good faith, reasonable discussions keeping in mind the proportionality factors that the Court considers, and that the Court will not require Merck to search every, or close to every, custodial and non-custodial file, but will require additional searches than previously completed given the significant posture of this MDL.</p> <p>To the extent the Parties cannot reach agreement with these directions then they may file the necessary motions. If the Parties are unable to reach agreement, their motion(s) must include specific requests and arguments as to each disputed discovery item (i.e. identification of the specific custodial or non-custodial files to be searched or not to be searched and the specific additional search terms to be run or not to be run, etc.).</p>
RFP No. 32	Merck's full regulatory file, including the Chemistry Manufacturing and Control ("CMC") section, in eCDT format.	GRANTED IN PART and DENIED IN PART. Plaintiffs' request for the CMC section of the regulatory file is denied. Plaintiffs failed to demonstrate that the specific information contained within the CMC section is relevant and proportional to the needs of this case. To the extent the information is relevant, it can be discovered through other means. As proposed by Merck during oral arguments, the Court will require Merck to provide the batch records for the vaccines given to Plaintiffs provided that the Plaintiffs provide the necessary information to Merck.

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		<p>Plaintiffs' request for the regulatory file in eCDT format is granted to the extent it already exists in such format. Specifically, any portions of the regulatory file that are already in the eCDT format must be reproduced in that eCDT format. Given the defenses, the regulatory file in native format is relevant and proportional to the needs of this MDL. The Court is not persuaded that the burden presented by Merck's counsel during oral arguments is necessary and unavoidable.</p>
RFP Nos. 45–49	All documents concerning Gardasil labels, including internal discussions and proposed revisions and redline edits concerning the labels.	<p>The Court finds Plaintiffs' requests on their face are overly broad. <i>Health & Beauty Techs., Inc. v. Merz Pharma GmbH KGaA</i>, No. 7:18-CV-117-FL, 2018 WL 6345369, at *7 (E.D.N.C. Dec. 5, 2018). (“As a practical matter, Defendants cannot search every email inbox of every employee.”). However, given the MDL posture, the need and proportionality for discovery in this case is greater than what Merck provided in single-plaintiff cases. Thus, the Court will require the Parties to meet and confer in an effort to reach agreement on additional search terms and/or running searches through additional custodial or non-custodial files for responsive documents to these requests. During these meet and confers, the Court expects both Parties to engage in the necessary discussions to facilitate meaningful negotiations, such as identifying specific, relevant custodial or non-custodial files where needed. The Court instructs both Parties to engage in good faith, reasonable discussions keeping in mind the proportionality factors that the Court considers, and that the Court will not require Merck to search every, or close to every, custodial and non-custodial file, but will require additional searches than previously completed given the significant posture of this MDL.</p> <p>To the extent the Parties cannot reach agreement with these directions then they may file the necessary motions. If the Parties are unable to reach agreement, their motion(s) must include specific requests and arguments as to each disputed discovery item (i.e. identification of the specific custodial or non-custodial files to be searched or not to be searched and the specific additional search terms to be run or not to be run, etc.).</p>
RFP Nos. 55–56	All documents and communications concerning Merck's causality assessments for Gardasil or any of its ingredients.	<p>The Court finds Plaintiffs' requests on their face are overly broad. <i>Health & Beauty Techs., Inc. v. Merz Pharma GmbH KGaA</i>, No. 7:18-CV-117-FL, 2018 WL 6345369, at *7 (E.D.N.C. Dec. 5, 2018). (“As a practical matter, Defendants cannot search every email inbox of every employee.”). However, given the MDL posture, the need and proportionality for discovery in this case is greater than what Merck provided in single-plaintiff cases. Thus, the Court will require the Parties to meet and confer in an effort to reach agreement on additional search terms and/or running searches through additional custodial or non-custodial files for responsive documents to these requests. During these meet and confers, the Court expects both Parties to engage in the necessary discussions to facilitate meaningful negotiations, such as identifying specific, relevant custodial or non-custodial files where needed. The Court instructs both Parties to engage in good faith, reasonable discussions keeping in mind</p>

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		<p>the proportionality factors that the Court considers, and that the Court will not require Merck to search every, or close to every, custodial and non-custodial file, but will require additional searches than previously completed given the significant posture of this MDL.</p> <p>To the extent the Parties cannot reach agreement with these directions then they may file the necessary motions. If the Parties are unable to reach agreement, their motion(s) must include specific requests and arguments as to each disputed discovery item (i.e. identification of the specific custodial or non-custodial files to be searched or not to be searched and the specific additional search terms to be run or not to be run, etc.).</p>
RFP Nos. 71–74	All documents and communications that relate to, discuss, or mention published articles or medical opinions (including, but not limited to, drafts and red-line versions) concerning Gardasil, or any of its ingredients, that Merck or its agents helped draft, edit, write, ghostwrite, ghost-edit, or finance.	<p>GRANTED IN PART. To the extent Merck has readily available lists of the names of its Gardasil key opinion leaders (KOLs) and their renumerations related to Gardasil, as Plaintiffs suggest in their reply, then Plaintiffs’ request is granted as to all Gardasil KOLs. Otherwise, as directed below, the Parties shall meet and confer on this issue.</p> <p>The Court finds Plaintiffs’ requests on their face are overly broad. <i>Health & Beauty Techs., Inc. v. Merz Pharma GmbH KGaA</i>, No. 7:18-CV-117-FL, 2018 WL 6345369, at *7 (E.D.N.C. Dec. 5, 2018). (“As a practical matter, Defendants cannot search every email inbox of every employee.”). However, given the MDL posture, the need and proportionality for discovery in this case is greater than what Merck provided in single-plaintiff cases. Thus, the Court will require the Parties to meet and confer in an effort to reach agreement on additional search terms and/or running searches through additional custodial or non-custodial files for responsive documents to these requests. During these meet and confers, the Court expects both Parties to engage in the necessary discussions to facilitate meaningful negotiations, such as identifying specific, relevant custodial or non-custodial files where needed. The Court instructs both Parties to engage in good faith, reasonable discussions keeping in mind the proportionality factors that the Court considers, and that the Court will not require Merck to search every, or close to every, custodial and non-custodial file, but will require additional searches than previously completed given the significant posture of this MDL.</p> <p>To the extent the Parties cannot reach agreement with these directions then they may file the necessary motions. If the Parties are unable to reach agreement, their motion(s) must include specific requests and arguments as to each disputed discovery item (i.e. identification of the specific custodial or non-custodial files to be searched or not to be searched and the specific additional search terms to be run or not to be run, etc.).</p>
RFP No. 10	All communications (either internally or with third parties) concerning replacing	The Court finds Plaintiffs’ requests on their face are overly broad. <i>Health & Beauty Techs., Inc. v. Merz Pharma GmbH KGaA</i> , No. 7:18-CV-117-FL, 2018 WL 6345369, at *7 (E.D.N.C. Dec. 5, 2018). (“As a practical matter, Defendants cannot search every email inbox of every employee.”). However,

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	any of the Gardasil ingredients.	<p>given the MDL posture, the need and proportionality for discovery in this case is greater than what Merck provided in single-plaintiff cases. Thus, the Court will require the Parties to meet and confer in an effort to reach agreement on additional search terms and/or running searches through additional custodial or non-custodial files for responsive documents to these requests. During these meet and confers, the Court expects both Parties to engage in the necessary discussions to facilitate meaningful negotiations, such as identifying specific, relevant custodial or non-custodial files where needed. The Court instructs both Parties to engage in good faith, reasonable discussions keeping in mind the proportionality factors that the Court considers, and that the Court will not require Merck to search every, or close to every, custodial and non-custodial file, but will require additional searches than previously completed given the significant posture of this MDL.</p> <p>To the extent the Parties cannot reach agreement with these directions then they may file the necessary motions. If the Parties are unable to reach agreement, their motion(s) must include specific requests and arguments as to each disputed discovery item (i.e. identification of the specific custodial or non-custodial files to be searched or not to be searched and the specific additional search terms to be run or not to be run, etc.).</p>
ROG No. 36	Provide a complete answer to Interrogatory 36 regarding the Gardasil label.	GRANTED IN PART. Merck's reference to large numbers of documents is insufficient to comply with Rule 33(d). The Court expects Merck to make a reasonable, good faith effort to respond to the interrogatory.
ROG Nos. 78-80	Provide a complete answer to Interrogatories 78-80 identifying third parties and employees.	GRANTED IN PART. Merck's reference to large numbers of documents is insufficient to comply with Rule 33(d). The Court expects Merck to make a reasonable, good faith effort to respond to the interrogatories.
ROG No. 86	Provide a complete answer to Interrogatory 86 regarding medical journal articles concerning Gardasil.	GRANTED IN PART and DENIED IN PART. The parties shall comply with the Court's directions regarding RFP Nos. 71-74. The Court expects Merck to make a reasonable, good faith effort to respond to the interrogatory. However, Plaintiffs' request for an "exhaustive list" is overbroad.
ROG No. 87	Provide a complete answer to Interrogatory 87 regarding a list of KOLs.	GRANTED IN PART. To the extent Merck has readily available lists of the names of its KOLs, then Plaintiffs' request is granted as to all Gardasil KOLs. Otherwise, the Parties shall comply with the Court's directions regarding RFP Nos. 71-74.

IV. CONCLUSION

IT IS, THEREFORE, ORDERED that Plaintiffs' Motion to Compel (Doc. No. 36) is
GRANTED IN PART and **DENIED IN PART**.

Signed: March 19, 2023

A handwritten signature in black ink, reading "Robert J. Conrad, Jr.", written over a horizontal line.

Robert J. Conrad, Jr.
United States District Judge

